IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and INTERMUNE, INC.,	)	
Plaintiffs,	)	
	)	C.A. No. 19-78 (RGA)
v.	)	CONSOLIDATED
AUROBINDO PHARMA LIMITED, et al.,	)	**REDACTED – PUBLIC VERSION**
Defendants.	)	

LETTER TO THE HONORABLE RICHARD G. ANDREWS FROM KAREN JACOBS IN OPPOSITION TO DEFENDANTS' DISCOVERY MOTIONS

MORRIS NICHOLS ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Karen Jacobs (#2881)
Cameron P. Clark (#6647)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com
cclark@mnat.com

Attorneys for Plaintiffs Genentech, Inc. and InterMune, Inc.

OF COUNSEL:

Mark E. Waddell
Warren K. MacRae
Ryan Hagglund
Kathleen Gersh
LOEB & LOEB LLP
345 Park Avenue
New York, NY 10154
(212) 407-4000

Alexandra Cavazos
Dan Liu
LOEB & LOEB LLP
10100 Santa Monica Boulevard, Suite 2200
Los Angeles, CA 90067
(310) 282-2000

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Dear Judge Andrews:

Plaintiffs InterMune, Inc. and Genentech, Inc. (collectively, "Plaintiffs") submit this letter in opposition to Defendants' discovery motions [D.I. 264].

I. Plaintiffs' Expert Reports

Plaintiffs respectfully request that Defendants' motion to preclude be denied in its entirety. First, Plaintiffs' experts did disclose opinions that pertain to objective indicia as well as infringement in their opening reports. Second, contrary to Defendants' assertions, nothing in the Scheduling Order [D.I. 19] precludes Plaintiffs' experts from now rebutting the particular obviousness theories advanced by Defendants – several of which Defendants advanced for the first time in opening reports. Plaintiffs' rebuttal evidence includes previously disclosed evidence, *inter alia*, relying on patent examiners' reasons for allowing the patents based on teaching away by the art and unexpected results, industry praise, skepticism, long-felt need, and copying. Defendants have been on notice of all this evidence since Plaintiffs' contention interrogatory responses served August 31, 2020. Defendants are also not prejudiced because (i) Defendants were able to explore the underlying evidence during fact discovery; (ii) their experts may serve reply reports; and (iii) Defendants may also depose Plaintiffs' experts.

Examples of some of the objective indicia evidence are described below. Plaintiffs cited these and other excerpts during meet and confers and in their March 29 letter. *See* Defendants' submission, D.I. 264, Exh D at 2[1]. That the expert opinions do not appear under formal headings, i.e. labelled "objective indicia," is of no moment as the opinions themselves are disclosed and Defendants can rebut them. *See Endo Pharms. Inc. v. Actavis Inc.*, C.A. No. 14-1381-RGA, D.I. 173 at 1 (D. Del. Feb. 8, 2017) [Exh 1] ("Plaintiffs' expert, it is asserted, has addressed neither [commercial success and long felt need]. Plaintiffs do not address either of these in their Opposition. They do state that their expert will state that the prior art taught away. He, of course, can testify to this, or to anything else that is in his expert report.")[2] Nor is this discovery motion the proper means to determine a merits issue of what can be considered as objective indicia.

Dr. Nathan's Opening Report [Exh 3[3]] describes the fatal progression of idiopathic pulmonary fibrosis ("IPF") [*Id.* ¶¶ 33-36] and states "[p]rior to the approval of pirfenidone in 2014 by the FDA, there were no drugs approved for treatment of IPF in the United States." *Id.* ¶ 37. He describes the elevated liver enzyme invention embodiments in the FDA-approved Esbriet® (pirfenidone) labeling ("package insert") [*Id.* ¶¶ 50-60] and describes how, "[p]racticing the methods … with respect to management of patients' elevations of AST and/or ALT … allows

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[1] For brevity, Plaintiffs are not summarizing the opening reports in their entireties. The excerpt of Dr. Nathan's Appendix D [in Exh 3] sets forth his review of the individual claims and summarizes his reasons for concluding that these claims cover the inventive methods embodied in the FDA-approved labeling, which Plaintiffs would rely on if Defendants contest nexus.

[2] *See* Exh 2, Brief of the *Endo* Plaintiffs, who had argued: "[w]hile Dr. Davies's 183-page initial expert report does not have a specific section entitled 'secondary considerations,' some of the topics in Dr. Davies's report are relevant to the factual underpinning for the secondary considerations analysis that the Court will conduct after trial."

[3] Large document exhibits are filed as excerpts with only the cited pages.

physicians, including myself" to intervene before patients experience elevations that require they be taken off the drug or, worse, "suffer irreversible liver damage to the point that he or she might have liver failure, need a liver transplant, or potentially die." *Id.* ¶ 62. "Also … the instructions in the prescribing information enable physicians to keep IPF patients who exhibit elevations of >3 but ≤5 x ULN in ALT and/or AST on pirfenidone therapy and avoid discontinuation of pirfenidone." *Id.* ¶ 63. Dr. Nathan further explains how these inventions improve treatment of IPF patients. *Id.* ¶ 65. He opines that actual clinical practice results are "an attestation to the instructions for dose adjustment and management for ALT and/or AST elevations … being a very effective strategy …" *Id.* ¶ 66. He describes the nature of the problem solved by the invention. *Id.* ¶¶ 71-75. Dr. Nathan adds that, "[i]rreversible liver injury with pirfenidone treatment is not a hypothetical risk. Serious cases of drug induced liver injury, including severe liver injury with fatal outcome, resulting from pirfenidone treatment have been reported …" *Id.* ¶ 76. [redacted]

Dr. Williams' Opening Report [Exh 4] describes Defendants' deliberate copying of the foregoing inventions (which include, e.g., the liver injury mitigation methods discussed by Dr. Nathan). *Id.* ¶¶ 86-96. [redacted] *Id.* ¶ 94. [redacted]

Plaintiffs identified additional objective indicia in their interrogatory responses, e.g. (i) contained in the patents' intrinsic records, including examiners' reasons for allowance, and (ii) other evidence that will be introduced through one or both inventor(s) at trial. *See* Interrogatory Resp. excerpts, Exh 5 at 19-28, 30-39; and inventor testimony excerpts, Exh 6 at 49:15-17, 73:4-25, 78:17-86:12, 131:14-132:9, 135:11-136:5, 144:14-145:13, 149:2-22, 168:1-17, and 191:5-22.

None of the *Pennypack* factors supports the extreme remedy Defendants seek in their motion. There is no prejudice or surprise when (a) Plaintiffs' opening reports disclose objective indicia that Drs. Nathan and Williams will present, and (b) Plaintiffs' interrogatory responses already disclosed the objective indicia Plaintiffs will introduce through the intrinsic patent record and inventor testimony - and Defendants also took the inventors' depositions.

There being no demonstrated prejudice or surprise here, there is nothing to cure. Indeed, the sole prejudice was to Plaintiffs when Defendants relied on all new obviousness combinations that they disclosed for the *first time* in their final invalidity contentions served just two weeks before opening reports were due, and as late as Defendants' opening reports themselves in several cases. *See* Plaintiffs concurrent discovery motion [D.I. 262]; *In re Chanbond, LLC Patent Litigation*, C.A. No. 15-842-RGA, 2019 WL 2098316 (D. Del. May 14, 2019) (permitting supplemental disclosure to respond to opponent's new theory).

There is no disruption to the schedule. Nor does Defendants' motion present evidence of any actual bad faith/willfulness. Rebuttal expert reports are due on May 5th and reply reports are on June 4th. Defendants prospectively accuse Plaintiffs of violating the Scheduling Order before Plaintiffs have served their rebuttal reports. In fact, Plaintiffs' experts properly offered opinions in their opening reports pertinent to objective indicia, among other things. Defendants will have a full opportunity to rebut the opening reports. Likewise, on May 5th, Plaintiffs' expert(s) will rebut Defendants' obviousness combinations after analyzing (a) the scope and content of the prior art, (b) differences between the prior art and the asserted claims, (c) the level of ordinary skill in the art, and (d) any objective indicia in the record. There also are 26 new prior art references that Defendants introduced in final contentions and opening reports. Some of the same back-and-forth between experts over what all the prior art teaches about motivation and reasonable expectation of success may also be relevant to objective indicia such as teaching away and unexpected results. Yet, Defendants propose to prospectively bar Plaintiffs' experts from considering and responding to all this new evidence. Plaintiffs respectfully request that the Court deny Defendants' motion.

II. Bradford Consulting Invoices

Plaintiffs also respectfully request that the Court deny Defendants' motion to compel.

Dr. Bradford led the development of Esbriet® (pirfenidone) at InterMune. Plaintiffs' counsel retained him as a consulting expert to assist with case preparation. He testified at deposition as both an inventor and Rule 30(b)(6) witness concerning certain aspects of InterMune's research and development. *See* Exh 6 at 187:11-25, 190:5-194:13. Notwithstanding that Defendants never served any written discovery directed to Dr. Bradford's compensation, he provided this information at his deposition [D.I. 264 Exh F]. Plaintiffs thereafter confirmed those amounts at Defendants' request [*Id.* Exh G]. Still not satisfied, Defendants then demanded production of invoices or a response to a sworn interrogatory. Plaintiffs nonetheless offered to provide this information in response to an interrogatory even though the parties agreed in the Protective Order not to seek such information. *See* D.I. 73 ¶ 3.5. All Plaintiffs asked was that Defendants likewise disclose the compensation of their experts prior to trial as required by FRCP 26 (b)(4)(c)(i) (discoverability of compensation paid for testifying expert's study or testimony), which likewise is relevant to bias. Defendants refused.

The Protective Order [D.I. 73] governs communications with and testimony that may be taken from consulting experts. *See id*. ¶¶ 3.5 and 3.6. The Order, (a) limits discovery that may be taken from consulting experts to only specific circumstances, and (b) protects communications with consulting experts, and other information, which "shall be treated as attorney work product." *Id*. Plaintiffs remain willing to provide an interrogatory response identifying compensation to Dr. Bradford, provided that Defendants likewise identify the compensation of their experts. But in any event, there is no basis for Defendants to demand unredacted invoices that may potentially disclose attorney-client communications containing descriptions of Dr. Bradford's consultations with Plaintiffs' counsel and disclose attorney work product. *TCL Comm'n Tech. Holdings, Ltd. v. Telefonaktiebolaget LM Ericsson et al.*, SA CV 14-00341-JVS (DFMx), D.I. 929 at 2 (C.D. Cal. July 1, 2016) [Exh 7] ("The Court agrees that statements and narratives in bills and invoices that reflect communications between [plaintiff's] attorney and its experts may be redacted. . . . Redacting such a narrative would not diminish the objective of the exception, which is to permit a 'full inquiry into such [compensation-related] sources of bias.'").

Respectfully,

/s/ Karen Jacobs

Karen Jacobs (#2881)

KJ/
Attachments
cc: All Counsel of Record (via electronic mail; w/attachments)